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Dkt. 2259/65532-A-PCT-US/JPW/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lawrence G. Lum et al.

Serial No.: 10/553,853 Examiner: Not Yet Known

Intl.

Filing Date: April 23, 2003 Art Unit: Not Yet Known

For : COMPOSITIONS AND METHODS FOR STEM CELL DELIVERY

1185 Avenue of the Americas New York, New York 10036

May 29, 2007

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit A). Copies of references 3-22 are attached hereto as Exhibits 1-20, respectively.

- 1. U.S. Patent No. 5,762,930, issued June 9, 1998, to Fanger et al.;
- 2. U.S. Patent No. 6,096,311, issued August 1, 2000, to Fanger et al.;
- 3. PCT International Search Report issued November 14, 2003 in connection with PCT International Application No.

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PCT/US2003/012679, filed April 23, 2003, PCT Publication No. WO/2003/091398 A3, published November 6, 2003, on behalf of Roger Williams Hospital et al. (Exhibit 1);

- 4. Communication Pursuant to Article 157(2)(a) EPC including Supplementary European Search Report issued February 15, 2007 in connection with European Patent Application No. EP 03 73 1044, filed April 23, 2003 on behalf of Roger Williams Hospital et al. (Exhibit 2);
- 5. European Application No. 88 108 793.6, filed on June 6, 1988, European Publication No. 0 294 703, published December 14, 1988, on behalf of Dana-Farber Cancer Institute, Inc. (Exhibit 3);
- 6. Almeida-Porada, G. et al. (1999) "Transplantation of Human Neuronal Stem Cells into Fetal Sheep Give Rise to Hematopoietic Cells In Vivo," Blood 94: 129a (abstract #567) (Exhibit 4);
- 7. Bjornson, C. et al. (1999) "Turning Brain Into Blood: A Hematopoietic Fate Adopted by Adult Neural Stem Cells In Vivo," Science 283:534-537 (Exhibit 5);
- 8. Ferrari, G. et al. (1998) "Muscle Regeneration by Bone
 Marrow-Derived Myogenic Progenitors," Science 279:1528-1530
 (Exhibit 6);

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Page 3

- 9. Gussoni, E. et al. (1999) "Dystrophin Expression in the mdx Mouse Restored by Stem Cell Transplantation," Nature 401:390-394 (Exhibit 7);
- 10. Jackson, K. A. et al. (1999) "Hematopoietic Potential of
 Stem Cells Isolated from Murine Skeletal Muscle," Proc.
 Natl. Acad. Sci. U.S.A. 96:14482-14486 (Exhibit 8);
- 11. Kawada, H. et al. (2001) "Bone Marrow Origin of
 Hematopoietic Progenitors and Stem Cells in Murine Muscle,"
 Blood 98:2008-2013 (Exhibit 9);
- 12. Krause, D. S. et al. (2001) "Multi-Organ, Multi-Lineage
 Engraftment by a Single Bone Marrow-Derived Stem Cell," Cell
 105:369-377 (Exhibit 10);
- 13. Lagasse, E. et al. (2000) "Purified Hematopoietic Stem Cells
 can Differentiate into Hepatocytes in vivo," Nat. Med.
 6:1229-1234 (Exhibit 11);
- 14. Lum, L. et al. (2001) "Activated T-Cell and Bispecific Antibody Immunotheraphy For High-Risk Breast Cancer," Acta Haematol. 105:130-136 (Exhibit 12);
- 15. Orlic, D. (2001) "Hematopoietic Cells Regenerate Infarcted
 Myocardium," Exp. Hematol. (Suppl) 29:4 (abstract #10)
 (Exhibit 13);

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Page 4

- 16. Orlic, D. et al. (2000) "Transplanted Hematopoietic Stem
 Cells Repair Myocardial Infarcts," Blood 96:221a (abstract
 #943) (Exhibit 14);
- 17. Petersen, B. E. et al. (1999) "Bone Marrow as a Potential Source of Hepatic Oval Cells", Science 284:1168-1170 (Exhibit 15);
- 18. Raso, V. et al. (1997) "Intracellular Targeting With Low pH-triggered Bispecific Antibodies," *Journ. Biol. Chem.* 272:27623-27628 (Exhibit 16);
- 19. Riedle, S. et al. (1998) "In Vivo Activation and Expansion of T Cells By a Bi-Specific Antibody Abolishes Metastasis Formation of Human Melanoma Cells in SCID Mice," Int. J. Cancer 75:908-918 (Exhibit 17);
- 20. Theise, N. D. et al. (2000) "Derivation of Hepatocytes from Bone Marrow Cells in Mice after Radiation-induced Myeloblation," Hepatology 31:235-240 (Exhibit 18);
- 21. Valtz, N. L. et al. (1991) "An Embryonic Origin for Medulloblastoma," New Biologist 3:364-371 (Exhibit 19); and
- 22. Wakitani, S. et al. (1995) "Myogenic Cells Derived from Rat Bone Marrow Mesenchymal Stem Cells Exposed to 5-Azacytidine," Muscle Nerve 18:1417-1426 (Exhibit 20).

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An International Search Report was issued on November 14, 2003 in connection with PCT International Application No. PCT/US2003/012679, filed April 23, 2003, of which the subject application is a §371 national stage application. A copy of the Search Report is attached hereto as **Exhibit 1**. Above-listed references 1, 2, 5 and 18 were cited in the International Search Report.

European Patent Application No. EP 03 73 1044, filed April 23, 2003, is a related regional stage application claiming priority of PCT International Application No. PCT/US2003/012679. A Supplementary European Search Report was issued on February 15, 2007 in connection with European Patent Application No. EP 03 73 1044. A copy of the Supplementary European Search Report is attached hereto as Exhibit 2. Above-listed references 14 and 19 were cited in the Supplementary European Search Report.

Above-listed references 1 and 2 are U.S. patents. Accordindly, pursuant to 37 C.F.R. §1.98(a)(ii) copies of these patents are not required to be provided to the United States Patent and Trademark Office.

Applicants request that the Examiner review the references listed above and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned

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attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if fee any required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents P.O. Box 1450, Arlington, VA 22313-1450 for Patents,

White

. No. 28,678

Date

John P. White

Registration No. 28,678 Attorney for Applicants Cooper & Dunham LLP 1185 Avenue of the Americas New York, New York 10036 (212) 278-0400



S. Department of Commerce Patent and Trademark Office

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Application Number	10/553,853		
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First Named Inventor	Lawrence G. Lum		
Art Unit	Not Yet Known		
Examiner Name	Not Yet Known		
Attorney Docket No.	2259/65532-A-PCT-		

US/JPW/MVM

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)

			U.S. PATENT DOC	I
Examiner Initials	Cite No.1	Document Number Number-Kind Code ^{2 (if known)}	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	US 5,762,930	06-09-1998	Fanger et al.
	2	US 6,096,311	08-01-2000	Fanger et al.
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.FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.1	Foreign Patent Document Country Code ³ - Number ⁴ -Kind Code ^{5 (If known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T ⁶
	5	EP 0 294 703	12-14-1988	Dana-Farber Cancer Institute, Inc.	
EXAMINER SIGNATURE		DATE CONSIDERED			

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds of Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English Language Translation is attached.

Exhibit A

				Page 2	of 3
Form P1	O-144	19 U.S. Department of Commerce	Application Number	10/553,853	
		Patent and Trademark Office	Intl. Filing Date	April 23, 2003	3
			First Named Inventor	Lawrence G. L	um
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			Attorney Docket No.	2259/65532-A US/JPW/MVI	
		NON PATENT LITERATURE DO	OCUMENTS		
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of item (book, magazine, journal, serial, symposium, catalog, et publisher, city and/or country wh	c.) date, page(s), volume-iss ere published.	ue number(s),	T ²
	3	PCT International Search Report i in connection with PCT Internat PCT/US2003/012679, filed April 23 No. WO/2003/091398 A3, published behalf of Roger Williams Hospital	tional Applica , 2003, PCT Pub l November 6,	tion No. olication	
	4	Communication Pursuant to Article Supplementary European Search Rep 2007 in connection with European Page 3 73 1044, filed on April 23, 2 Williams Hospital et al.	ort issued Febr atent Application	uary 15, on No. EP	
	6	Almeida-Porada, G. et al. (1999) "'Neuronal Stem Cells into Fetal Hematopoietic Cells In Vivo," Bl #567)	Sheep Give	Rise to	
	7	Bjornson, C. et al. (1999) "Turni Hematopoietic Fate Adopted by Adu Vivo," <i>Science</i> 283:534-537	ng Brain Into lt Neural Stem	Blood: A Cells in	
	8	Ferrari, G. et al. (1998) "Muscl Marrow-Derived Myogenic Progenito 1530	e Regeneration ors," <i>Science</i> 2	by Bone 79:1528-	-
	9	Gussoni, E. et al. (1999) "Dystromdx Mouse Restored by Stem Cell To 401:390-394	pphin Expressio ransplantation,	n in the " <i>Nature</i>	
	Jackson, K.A. et al. (1999) "Hematopoietic Potential of Stem Cells Isolated from Murine Skeletal Muscle," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 96:14482-14486				
	11	Kawada, H. et al. (2001) "Bo Hematopoietic Progenitors and S Muscle," <i>Blood</i> 98:2008-2013	Stem Cells in	Murine	-
	12	Krause, D.S. et al. (2001) "Mult Engraftment by a Single Bone Marr Cell 105:369-377	row-Derived Ste	m Cell,"	
		Lagasse, E. et al. (2000) "Purif Cells can Differentiate into Hepa Med. 6:1229-1234			

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DATE CONSIDERED

Med. 6:1229-1234

EXAMINER

SIGNATURE

Form PT	O-144	9 U.S. Department of Commerce	Application Number	10/553,853	
Patent and Trademark Office INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)			Intl. Filing Date	April 23, 2003	
		First Named Inventor	Lawrence G. Lum		
		Art Unit	Not Yet Known		
		Examiner Name	Not Yet Known		
Attor			Attorney Docket No.	2259/65532-A-PCT- US/JPW/MVM	
		NON PATENT LITERATURE DOC	CUMENTS		
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of th item (book, magazine, journal, serial, symposium, catalog, etc.) publisher, city and/or country wher	date, page(s), volume-iss		
	14	Lum, L. et al. (2001) "Activated		specific	
		Antibody Immunotheraphy For High-Ris Haematol. 105:130-136			
	15	Orlic, D. (2001) "Hematopoietic Cell Myocardium," Exp. Hematol. (Suppl)			
		Orlic, D. et al. (2000) "Transplant			
	16	Cells Repair Myocardial Infarcts," # #943)			
	17	Petersen, B.E. et al. (1999) "Bone Source of Hepatic Oval Cells", Scie			
	18	Raso, V. et al. (1997) "Intracellu pH-triggered Bispecific Antibodies 272:27623-27628			
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	20	Theise, N.D. et al. (2000) "Derivati	er Radiation		
	21	Valtz, N.L. et al. (1991) "An Medulloblastoma," <i>New Biologist</i> 3:3	Embryonic Or:	igin for	
	22	Wakitani, S. et al. (1995) "Myogen Rat Bone Marrow Mesenchymal Stem Azacytidine," <i>Muscle Nerve</i> 18:1417-	Cells Expose		
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